DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

M2318N

JAN 20 1999

WARNING LETTER

VIA FEDERAL EXPRESS

Ref:OC:I1-1810

Mr. Theodore A. Boutacoff
President & CEO
IRIS Medical Instruments, Inc.
1212 Terra Bella Avenue
Mountain View, California 94043-1824

Dear Mr. Boutacoff:

This letter is written to advise you of noncompliances with the Federal laser product performance standard encountered during review of the report on the OcuLight GL Laser System, dated November 24, 1997, Accession Number 9010164-14. Ophthalmic and dermatological lasers for human use are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

21 CFR 1040.11(a)(2). Neither the OcuLight GL Operator's Manual submitted in the laser product report nor the OcuLight GL Operator's Manual submitted in the March 1996 510(k) includes adequate calibration procedures, required to be supplied with each Class III and IV medical laser product. A calibration check as included in Appendix A is not sufficient.

Although we would not object to your inclusion of statements such as you have to the effect that only authorized representatives of IRIS Medical may perform the procedure and that user recalibration would invalidate the warranty, the requirement is clear that the instructions must be supplied to the purchaser.

The requirement does not apply to your veterinary model. You will recognize, however, that this requirement is virtually identical in the IEC 825 standard for medical lasers.

Section 538(a) of the Act, Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard.

This section also prohibits any manufacturer from failure to establish and maintain required records or from failure to submit required reports. Failure to respond to this letter may be considered to be in violation of section 538(a)(4) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. You should take prompt action to correct this deficiency. Failure to promptly correct this deficiency may result in regulatory action being initiated by the FDA without further notice. These actions may include, but are not limited to, seizure, injunction, and/or imposition of civil penalties as provided for in section 539.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

   a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

   b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following noncompliance with the regulations regarding reports was observed:

> 21 CFR 1002.13. Annual Reports. An Annual report has not been received since your 1994-1995 Annual Report submitted in August 1995.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

We also have the following questions and requests for more information:

1. The Operator's manual mentions a fiber optic connector with electronic detection at the fiber port, however, your response to Part 7.2 of the report says that there are no safety interlocks. All delivery accessories that are intended to be connected and disconnected by the user must be interlocked in order to comply with 21 CFR 1040.10(f)(2)(iii). Please note, this interlock must be either fail-safe or redundant for Class IV levels.

   Please submit a description demonstrating how your system complies.

2. With regard to the Warning Logotype label shown on the OcuLight GL sales brochure, dated 9/96, it carries the phrase, "visible and/or invisible laser radiation," which may not be appropriate on this label, if the infrared Nd:YAG beam would be accessible only during service. The main purpose of the Warning Logotype label, both on brochures as well as on the product, is to inform as to user-accessible radiation and to assist the user in selecting appropriate protective eyewear.

   Is there a low level of radiation being emitted at 1064nm? If the level is above Class I the Warning label should identify that wavelength as well. If so, please provide an explanation as to the necessity and utility of the infrared radiation access.

   Perhaps this brochure is obsolete since it also carries your firm's old address. Please submit a current version demonstrating compliance with 21 CFR 1040.10(h)(1) and any labeling modifications you may decide to make.

3. The manufacturer's address printed on the OcuLight's back label also carries 340 Pioneer Way. Is that still a current address? If not, please arrange to have the address updated at the next printing and submit a revision as a report supplement.

4. Please review the labeling and user instructions for the OcuLight SL series as well and confirm compliance or submit revised information as a report supplement.

Furthermore, if you have other laser products in production or distributed for clinical studies a laser product report is also required. Please clarify your marketing status.

Your response, clearly referencing Accession Number 9010164, should be sent to: General Surgery Devices Branch, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. If you have further questions on these requirements, please contact Ms. Cory Tylka of the General Surgery Devices Branch at phone: 301-594-4595, ext. 170, or FAX: 301-594-4636.

Sincerely yours,

Gerri J. Melton

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Mr. Daniel R. Simin
Regulatory Compliance Manager
IRIS Medical Instruments, Inc.
1212 Terra Bella Avenue
Mountain View, California 94043-1824

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